



Bergen Brunswig Corporation

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September 30, 1996

Mr. G. Thomas Gitchel Chief, Liaison and Policy Section Drug Enforcement Administration United States Department of Justice Washington, DC 20537

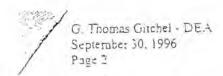
Dear Mr. Gitchel,

The purpose of this letter is to introduce the Drug Enforcement Administration (DEA) to an innovative new system under development by Bergen Brunswig Drug Company (BBDC) to monitor and report customer orders of controlled substances which fit the suspicious order criteria outlined in 21 CFR § 1301.74 (b).

By way of background, as you know BBDC participated in the development of a model Excessive Purchase Report now in use by many distributor registrants. As used by BBDC, the Excessive Purchase Report lists total customer purchases for the reported month which exceed pre-determined multiples of the average monthly purchases of BBDC's total customer base. The program identifies purchases by individual DEA Drug Code and reads BBDC's sales files to calculate averages to be used as reporting criteria. The printed report (actually a series of reports) separates pharmacy registrants and hospital registrants, and further separates purchases by ARCOS class substances and non-ARCOS class substances within the respective pharmacy and hospital reports. This report is produced in hard-copy form monthly and is sent via certified mail to each DEA Field Office having responsibility for the reporting BBDC locations.

While feedback from different DEA users over the years has generally confirmed our belief that this report, standing alone, is a useful law enforcement tool, BBDC's suspicious order compliance program also involves the telephonic reporting of customer orders to DEA. In an average year, BBDC logs over twelve thousand (12,000) telephone calls to DEA Field Offices nationwide to orally report customer orders of controlled substances which it believes could fit the suspicious order criteria set forth in § 1301.74 (b). In nearly every instance, the telephonic contacts are made to report orders which later appear on the month-end Excessive Purchase Report sent to DEA.

As you may imagine given the sheer number of BBDC's contacts, DEA Field Office response to the frequency and mariner of BBDC's contacts has been varied. Some Field Offices have insisted that BBDC not telephonically report suspicious orders at all, but rather



to mail or fax copies of the order documents, 222 Forms or invoices to them instead. Some offices have diplomatically attempted to offer guidance as to the types of orders that their office would deem to be "reportable" in an effort to limit the number of telephone contacts. These telephone contacts are inefficient, burdensome and costly both for BBDC and DEA, as the telephone calls tie up DEA Investigator time and consume precious administrative resources.

I could appreciate DEA's belief that 12,000 BBDC telephone calls per year may be "over doing it," if not for the fact that the regulations clearly place the responsibility solely on the registrant to disclose any orders which fit the suspicious order criteria, and it has always been BBDC's position to adopt a conservative and thorough approach on matters involving controlled substance regulatory compliance.

In June 1995, Steve Harrold, BBDC Director, Corporate Security, attended the DEA-Industry Conference held in Naples, Florida. At this conference, in the Workshop entitled "Improving Utilization of Existing Technology to Meet DEA Requirements" led by Michael Moy, Mr. Harrold reported on the issue of telephonic suspicious order reporting and the consequent requests BBDC had received from various DEA Field Offices to limit suspicious order reports by telephone or to report orders in other ways (e.g. sending copies of orders by U.S. Mail, Fax, etc.). It was Mr. Harrold's impression that DEA would be amenable to exploring the concept of electronic transmission of suspicious orders.

Against this backdrop, BBDC set to work on the development of a suspicious order reporting program that would provide better quality information to DEA in a more efficient manner.

Our plan involves the creation of a computer program that compares a customer's controlled substance orders (expressed in metric units of the active ingredient) against a standard representing an average of the customer's prior four months of orders. Customer's whose orders exceed by a specified percentage their prior four month average order history would be printed on a summary report. BBDC's mainframe computer in Orange, California would automatically fax this report simultaneously to each respective DEA Field Office daily in the early AM hours after the distribution center has completed order processing activities. When DEA offices open each day, the summary report would be waiting for their review. DEA offices could also elect to receive a month-end version of this report via U.S. Mail. The summary report would show the customer name, address, DEA Number, Item Description, NDC Number, Order Date, Active Ingredient Volume Ordered, Active Ingredient Shipped and Customer "Allowance" (i.e. average of customers' prior four months orders).

While the current month-end report compares a customer's <u>purchases</u> against an average of calendar month sales to all like customers, the proposed report would compare a customer's daily <u>orders</u> against <u>that customer's prior orders</u>. This analysis would theoretically spot a customer who orders a singularly large amount of controlled substances. The current month-end report would continue to look at the customer's purchases in light of the entire customer base.

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Our intent is to receive DEA's permission to replace our current manner of daily suspicious order reporting (e.g. U.S. Mail; Telephone Calls) with this daily electronic facsimile report. We would like to have DEA input on the final product because DEA will be the primary users. One suggestion would be to coordinate with one of your Field Offices, perhaps the Los Angeles Office, to meet with our project development team. Your field office could beta test the report and provide us with input on aesthetics and content. There are some key questions that DEA would need to provide input on before the report is finalized. One question would be the assignment of the percentage value that a customer's order would have to exceed before that order would appear on the report. This value would directly impact the size of the report. Working with DEA's input, we hopefully will identify the optimum percentage value that will yield DEA the highest quality information without sacrificing administrative cost and efficiency. Once the Field Office test is concluded and the recommendations incorporated into the final product, then we can coordinate with your office to introduce the report to the entire DEA system.

Tom, we are excited about this opportunity to make constructive changes in our suspicious order reporting program. By working in a partnership with your office, we can perhaps lead the way to developing a new system that everyone feels good about.

I will schedule a call to your office in about two weeks to follow-up on this letter and to speak with you about how we can move forward.

Sincerely,

Chris Zimmerman

Manager, Corporate Security

SENDER: Complete items 1 and/or 2 for additional services. Complete items 3, 4a, and 4b. Print your name and address on the reverse of this form so the card to you. Attach this form to the front of the mailpiece, or on the back if spermit. Write 'Return Receipt Requested' on the mailpiece below the a The Return Receipt will show to whom the article was defivered delivered.	space does not	I also wish to receive the following services (for an extra fee): 1. ☐ Addressee's Addre
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U.S. Department of Justice

Drug Enforcement Administration

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CORPORATE SECURITY

Washington, D.C. 20537

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Mr. Chris Zimmerman Manager, Corporate Security Sergen Brunswig Corporation 4500 Metropolitan Drive Orange, California 92668

Dear Mr. Zimmerman:

Reference is made to your recent letter in which you requested that Bergen Brunswig be permitted to replace its current telephonic reporting of suspicious orders with a daily report transmitted by facsimile.

We have reviewed your proposal and feel that it could be a viable alternative to the current system. It is our understanding that a computer program has been created that can compare a customer's controlled substance orders to an average of the customer's orders for the prior four months. Customers' orders that exceed their four month average order history by an as yet unspecified percentage would be shown on a summary report that would be sent to the appropriate Drug Enforcement Administration (DEA) field office on a daily basis. As proposed, the summary report would include the customer's name, address and DEA number; a description of the item ordered; the NDC number; date ordered; active ingredient volume ordered and shipped; and the customer's "allowance" or average order.

We note that, unlike the program that generates Bergen Brunswig's monthly suspicious order report, the new program will compare the customer's order to his or her previous orders rather than to orders placed by other customers. It is therefore requested that each DEA office continue to be provided with the monthly reports in addition to the daily facsimile reports. It would also be helpful to our investigators if the quantity of drugs ordered were expressed in dosage units rather than by the weight of the active ingredient.

We agree that it would be prudent to test this new program before instituting it nationwide and concur with your suggestion to use the DEA Los Angeles Division office for the beta test. We would



Mr. Chris Zimmerman

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appreciate it if you would postpone starting the testing until after February 1, 1997, as Ms. Betsy Willis, who has been selected for the Diversion Program Manager position in the Los Angeles Field Division, will not be reporting for duty until the end of January. It is suggested that you contact Ms. Willis after January 20, 1997 to discuss this matter further. Ms. Willis may be reached at (213) 894-4015 after that date.

We look forward to working with you on this new project which we, too, hope will lead to a more efficient suspicious order reporting system. If you have any questions please let me know.

Sincerely

G. Thomas Gitchel, Chief Liaison and Policy Section Office of Diversion Control



U. S. Department of Justice

Drug Enforcement Administration

Washington, D.C. 20537

TUL 2 3 1998

Chris Zimmerman, Director Regulatory Compliance and Security Services Bergen Brusnwig Corporation 4000 Metropolitan Drive Orange, CA 92868

Dear Mr. Zimmerman:

This is to grant approval of your request to implement on a nationwide basis your newly developed system to identify and report suspicious orders for controlled substances and regulated chemicals, as required by Federal regulation. DEA managers who have been involved with the testing of the system have relayed their positive opinions regarding its ability to provide information in a fashion which is not only useful overall, but is also responsive to the needs of individual DEA offices.

We appreciate the efforts you have undertaken to develop this improved system and apologize for the lengthy approval process. It did not seem appropriate to grant this approval prior to the conclusion of the Suspicious Order Task Force formed as a result of the Methamphetamine Control Act. Thank you for your patience in this matter.

If you have any questions, please do not hesitate to call at (202) 307-7297.

Sincerely,

Patricia M. Good, Chief Liaison and Policy Section Office of Diversion Control



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